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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/533,928
Filing Date: July 29, 2005
Appellant(s): BERTHON-JONES ET AL.

John P. Darling
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 29, 2009 and the replacement sections of the Appeal Brief filed August 12, 2009 appealing from the Office action mailed November 24, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

WO 02/45784	AMARASINGHE ET AL.	6-2002
2003/0089373	GRADON ET AL.	5-2003
5,975,079	HELLINGS ET AL.	11-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

1. Claims 19-20, 22-23, 27, and 34-42 rejected under 35 U.S.C. 102(a) as being anticipated by Amarasinghe et al., (WO 02/45784).

Regarding claim 19, Amarasinghe discloses a mask assembly (10) for application of non-invasive positive pressure ventilation to a patient, comprising: a frame (figure 4) including a main body (13) including at least one aperture (hole in 13) configured to receive a supply of breathable gas under pressure, said frame including at least one selected portion (12) provided to the main body, said selected frame portion being adjustable relative to the main body; and a cushion (16) provided to the frame, the cushion being structured to provide an interface with the patient (figure 2), wherein said at least one selected frame portion (12) is engaged with the cushion (by wrapping around the cushion as seen in figure 2) so that the cushion is adjustable (on and off of patient via straps connecting 12) in accordance with a position of said at least one selected frame portion relative to the main body (12), and said cushion, upon application of positive pressure, applying a force to the patient, said force being adjustable in accordance with 1) the position of said at least one selected frame portion

relative to the main body for a given value of said positive pressure (via the tightening of the straps as positive air flow pressure increases); and/or 2) variations in the positive pressure (as the positive air flow is increase, the straps will tighten and when the air flow is decreased to straps will loosen).

Regarding claim 20, Amarasinghe discloses a mask assembly with at least one headgear connector portion provided to said at least one selected frame portion (15), said frame portion adapted to be movable in accordance with change in headgear strap tension to thereby adjust the force applied to the sides of the patient's nose and/or face in use (via adjusting the straps). See: figure 2.

Regarding claim 22, Amarasinghe discloses a mask assembly wherein the at least one selected frame portion includes a flexible member supporting the cushion (15 supports the cushion by wrapping around it when the straps are fitted around a users head). See: figure 2.

Regarding claim 23, Amarasinghe discloses a mask assembly with a main body (13) and the at least one selected frame portion (12) which are provided as two separate parts that are coupled to one another. See: page 6, line 27 –page 7, line 6 and figure 4.

Regarding claim 24, there is no structural limitation added to this claim. It is the examiner's position that the main body and the selected portion are moveable by a camming mechanism. Since a cam is merely a projecting part of a rotating wheel or shaft that strikes a lever at one or more points on its circular path, if a cam were to contact the mask, or a package containing the mask, the main body and the selected

portion would be movable by a camming mechanism. Since the camming mechanism is not part of the claimed apparatus, and the main body and the at least one selected frame portion are deemed to be moveable by a camming mechanism, the apparatus disclosed by Amarasinghe meets the claim.

Regarding claim 27 Amarasinghe discloses a mask assembly with at least one selected frame portion that includes lateral sides (15) of the frame that are made of a flexible material. See: page 7, lines 21-27.

Regarding claim 34, Amarasinghe discloses a mask assembly (10) for application of non-invasive positive pressure ventilation to a patient, comprising: a frame (figure 4) including a main body (13) having at least one aperture (hole in 13) configured to receive a supply of breathable gas under pressure, said frame including a selected frame portion (12) provided to the main body, said selected frame portion being adjustable relative to the main body (it can be attached and detached from the 13); and a cushion provided to the frame (16), the cushion being structured to provide an interface with the patient (figure 2), wherein the selected frame portion is engaged with the cushion so that the cushion is adjustable in accordance with the position of the selected frame portion relative to the main body, and wherein the selected frame portion includes each lateral side of the frame (15), and the selected frame portion is bendable to cause each lateral side of the frame to push against sides of the cushion (12 is a bendable metal).

Regarding claim 35, Amarasinghe discloses a mask assembly with a selected

frame portion (12) that includes a flexible member (20) supporting the cushion. See: page 7, lines 8-20.

Regarding claim 36, Amarasinghe discloses a mask assembly wherein the main body is relatively stiffer than the flexible member. See: page 30, lines 29-30.

Regarding claim 37, Amarasinghe discloses a mask assembly with a main body (13) and a selected frame portion (12) that are provided as two separate parts that are coupled to one another. See: page 6, line 27 - page 7, line 6 and figure 4.

Regarding claim 38, Amarasinghe discloses a mask assembly wherein the selected frame portion (12) includes lateral sides of the frame (15) which are made of a flexible material (12 is a bendable metal).

Regarding claim 39, Amarasinghe discloses a mask assembly with a selected frame portion that is bendable about a longitudinal axis of the frame (12 is a bendable metal).

Regarding claim 40, Amarasinghe discloses a mask assembly with a selected frame portion (12) that includes side wing portions (15) which are movable relative to the main body to adjust the sides of the cushion (16).

Regarding claim 41, Amarasinghe discloses a mask assembly wherein each of the side wing portions are adjustable into a plurality of positions (12 which forms 15 is bendable).

Regarding claim 42, Amarasinghe discloses a mask assembly with a cushion that is adapted to provide a seal with the patient's nose (16 forms a seal with the user's face, which includes the user's nose).

Regarding claim 43, the at least one selected frame portion (12) is adjustable (it is a malleable wire that would deform the cushion with enough applied force) to deform the cushion to adjust the fit and/or seal of the cushion on the patient's face. See: figure 2.

Regarding claims 44, the selected frame portion (12) is adjustable (it is a malleable wire that would deform the cushion with enough applied force) to deform the cushion to adjust the fit and/or seal of the cushion on the patient's face. See: figure 2.

Claim Rejections - 35 USC § 103

2. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amarasinghe et al., (WO 02/45784), as applied to claim 19 and 34 above, in view of Gradon et al., (2003/0089373).

Amarasinghe discloses all the limitations of claim 21 except the knob to change the relative positioning between the main body and the frame portion.

Gradon teaches a knob (440) that is used to adjust the bridge member (430). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mask assembly disclosed by Amarasinghe by replacing the stabilizing forehead portion of Amarasinghe with the adjustable forehead stabilizing portion as taught by Gradon because of the reasonable expectation of obtaining a mask assembly that could be adjusted easily and quickly without having to undue the straps.

3. Claims 25-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amarasinghe et al., (WO 02/45784), as applied to claim 19 above, in view of Hellings et al., (5,975,079).

Amarasinghe discloses all the limitations of claims 25-26 and 28 except the cushion with an inflatable unit that adjusts the size of the nasal bridge and the element providing for multiple stiffening rates of the cushion .

Hellings teaches a mask that is curved and contoured around the mouth and nasal bridge with an inflatable cushion. The reference teaches applying the mask to a user's face and then inflating the cushion, to provide a pneumatic seal. See: col. 3, lines 48-65.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mask disclosed by Amarasinghe by using an inflatable cushion as taught by Hellings, because of the reasonable expectation of obtaining a mask with a pneumatic seal while simultaneously alleviating orbital irritation and eliminating ocular pressure.

Regarding claim 28, the stiffening rate of the cushion taught by Hellings is directly attributable to the rate the gas is supplied to the mask. Thus, by adjusting the gas delivery rate, the cushion stiffening rate would also be adjusted. Thus, the combined references teach a cushion with at least one element providing for multiple stiffening rates as claimed.

(10) Response to Argument

Appellants argument to the rejection of claims 19-20, 22-23, 27, and 34-42 rejected under 35 U.S.C. 102(a) as being anticipated by Amarasinghe et al., (WO 02/45784) have been fully considered; however, they have not been found convincing.

Appellants argue on page 14, lines 15-18 that "Amarasinghe et al. do not anticipate claim 19 because Amarasinghe et al. do not disclose or suggest, at least, at least one selected frame portion engaged with the cushion so that the cushion is adjustable in accordance with a position of the at least one selected frame portion relative to the main body of the frame." However, the examiner respectfully disagrees.

The brace (12) is a malleable wire that is engaged with a cushion (via strap and a shell) and the brace is easily maneuvered by hand and Amarasinghe specifically shows portions (15) of brace (12) wrapping around the cushion (16) in figure 2. Therefore, the brace (12) is structured to engage the cushion (16) via shell (13) and tightening of the straps; and the tightness of the cushion would inherently be adjusted via the straps connected to brace (12). See: page 5, lines 4-19 of Amarasinghe. Moreover, upon positive pressure being applied to the mask, a pressure differential would inherently be created and by the mask being strapped to a patient (figure 2) the cushion would inherently apply a force to the patient by virtue of it being strapped to the patient. This pressure applied to a patient would then either be increased or decreased by tightening or loosening of the straps connected to the brace (12).

Appellants argument on page 15, second paragraph, that "The brace 12 of Amarasinghe et al. is not 'wrapped around' the cushion 16, as the brace head strap

attachment points 15 of the brace 12 extend away from, and do not engage, the cushion 16 as shown, for example, in Figs. 3-5 of Amarasinghe et al", has not been found convincing. As noted in the advisory action mailed March 27, 2009, The selected frame portion (brace) 12 of Amarasinghe is engaged with the cushion (16) via the main body (13) and by wrapping around the cushion as seen in figure 2. Moreover, Amarasinghe discloses on page 8, lines 8-16 that "It is also intended that the brace could be configured so as to engage brace receiving features that may be provided by a mask cushion clip. In this way the brace may be accurately positioned relative to the mask frame while serving to secure the cushion clip and cushion to the mask frame." Thus, it is clear that Amarasinghe discloses at least one selected frame portion (12) engaged with the cushion (16) via the main body or a cushion clip.

Regarding Appellants argument that even if the brace head strap attachment points 15 of the brace 12 did engage the mask cushion 16, such engagement would not adjust the cushion in accordance with a position of the brace 12 relative to the mask shell 13, the examiner respectfully disagrees.

Regarding the claimed limitation that the cushion is adjustable (capable of being adjusted) in accordance with a position of the at least one selected frame portion relative to the main body of the frame; it is the examiner's position that the cushion (which is attached to and forms the shape of a users face in figure 12) is adjustable (capable of being adjusted) by taking the straps on and off the patient; particularly given the malleability of the brace and the brace being detachably connected to the mask. This can be easily visualized by looking at figure 2 of Amarasinghe, with the mask

placed on a users face. When the mask is initially placed on a user, the cushion is loosely fitted to a user's face. When the straps are tightened, pressure is applied to the brace 12, which then adjusts the cushion via the applied pressure, relative to the main body, as claimed.

Regarding Appellants argument on page 16, last paragraph to page 17, first paragraph, that figures 2-5 of Amarasinghe clearly show that the brace 12 and the brace headgear strap attachment points 15 of the brace 12, do not contact the cushion 16, Appellants are reminded that they have agreed that "the claim does not require the frame portion being directly in contact with the cushion." See: last paragraph on page 6, of the Pre-Appeal Brief filed March 24, 2009. Thus, it is the examiners position that the brace 12 is "engaged" to with the cushion so that the cushion contact between the brace, as described on page 5, lines 4-18 of Amarasinghe.

Regarding Appellants argument that the brace of Amarasinghe assumes a fixed position with respect to the mask shell and the cushion of Amarasinghe cannot be adjusted in accordance with a position of the brace 12 relative to the mask shell 13 as the position of the brace 12 is fixed relative to the mask shell 13.

Appellant is directed to the language used by Amarasinghe on page 5, lines 4-18:

The invention includes the incorporation of a brace into the mask which is independent of the mask shell, said brace being adapted in use to be held in a **substantially fixed position** relative to the mask shell and to accommodate the attachment of at least part of the headgear. Emphasis added.

The present invention enables **the attachment points for headgear to be determined and varied in a physical or temporal sense independently of the mask shell configuration**. Emphasis added.

The invention broadly resides in a brace for a patient airway interface, **the brace being shaped so as to be retainingly engageable with the interface** and providing at least one formation for engagement with a headgear member. Emphasis added.

Preferably the brace includes an elongate member shaped so as to be engageable by formations on said interface. Emphasis added.

The invention also broadly resides in a brace for a patient airway interface, **the brace being shaped so as to be retainingly engageable with the interface, the brace further including a formation disposed for engagement with the patient's forehead.** Emphasis added.

Regarding Appellants argument in the last paragraph of page 18 of the Appeal Brief, that the prior art reference does not disclose the identical invention recited in claim 19, including a frame including a main body having at least one selected frame portion engaged with a cushion so that the cushion is adjustable in accordance with a position of the at least one selected frame portion relative to the main body, the examiner respectfully disagrees.

Amarasinghe discloses a mask assembly (10) for application of non-invasive positive pressure ventilation to a patient, comprising: a frame (figure 4) including a main body (13) including at least one aperture (hole in 13) configured to receive a supply of breathable gas under pressure, said frame including at least one selected portion (12 is a malleable wire) provided to the main body, said selected frame portion being adjustable (the attachment points for headgear to be determined and varied in a physical or temporal sense independently of the mask shell configuration) brace being shaped relative to the main body.

Regarding Appellants argument to the rejection of claim 20, on page 21, line 4 - page 21, line 16, that there is nothing in this disclosure of Amarasinghe that discloses or suggests that the brace 12 includes at least one headgear connector portion that is

adapted to be movable (capable of being moved) in accordance with a change in headgear strap tension to thereby adjust the force applied to the patient's nose and/or face in use. Appellants' attention is drawn to the page 5, lines 4-18 of Amarasinghe and are reminded that brace 12 is described as being a "malleable wire." See: page 7, lines 3-20 of Amarasinghe.

Appellants argument to the rejection of claim 22 has not been found convincing. Appellant argues that Amarasinghe et al. does not show the headgear attachment points 15 "wrapped around" the cushion 16 because Fig. 4 of Amarasinghe et al., the headgear strap attachment points 15 clearly do not "wrap around" the cushion 16. However, Appellant's attention is drawn to the clear description by Amarasinghe that "the brace being shaped so as to be retainingly engageable with the interface, the brace further including a formation disposed for engagement with the patient's forehead." Therefore, it is clear that the brace is not only engaged with the interface, it also wraps around the sides of it, where the brace contacts the patient's forehead.

Appellants argument, to the rejection of claim 23, on page 23, second full paragraph, that the brace 12 of Amarasinghe et al. does not correspond to the at least one selected frame portion of claim 23 and base claim 19 because the brace 12 of Amarasinghe et al. does not engage the cushion 16, as recited in base claim 19 has not been found convincing.

As noted above, the brace is engaged to the cushion and the brace is adapted in use to be held in a substantially fixed position relative to the mask shell and to accommodate the attachment of at least part of the headgear with the attachment points

for headgear to be determined and varied in a physical or temporal sense independently of the mask shell configuration. See: Amarasinghe page 5, lines 4-18.

Appellants argument on page 24, line 1 to the end of page 25 to the rejection of claim 24, based on the claims recitation that the main body and the at least one selected frame portion are movable (capable of being moved) by a camming mechanism have not been found convincing. The examiner maintains that a camming mechanism is not positively recited as part of the mask assembly and that the claim merely requires the main body and the at least one selected frame portion are movable (capable of being moved) by a camming mechanism (either intrinsic or extrinsic to the mask assembly). Thus, in response to Appellants stating that "It is apparently the position of the Examiner that there are some 'magic words' that are required in order to claim that the mask assembly includes a camming mechanism", the examiner has simply interpreted the claims as presented by Appellant which do not positively recite a camming mechanism as part of the mask assembly. Again, claim 24 merely recites the main body and the at least one selected frame portion are movable (capable of being moved) by a camming mechanism.

Regarding claim 27, Appellant argues, on page 26, line 1 - page 27, line 9, that Amarasinghe does not disclose at least one selected frame portion including each lateral side of a frame being made of a flexible material. However, the examiner respectfully disagrees. Amarasinghe discloses a malleable wire (constructed of 2.5mm gauge mild steel wire) as forming the brace (12). Mild steel has a relatively low tensile strength and is malleable and therefore meets the limitation of "being made from a

flexible material" as the low tensile strength malleable steel is capable of being flexed (i.e. able to bend without breaking).

Regarding claim 34, Appellant argues, on page 27, line 10 - the end of page 28 that Amarasinghe does not disclose or suggest that the brace engages the cushion or that the brace 12 is bendable to cause lateral sides of the shell 13 to push against sides of the cushion 16. However, the examiner respectfully disagrees. As discussed above, Amarasinghe discloses a brace engaged with a cushion and the claim 34 does not required direct engagement and/or direct contact of the frame selected portion with the cushion. Claim 34 required the selected frame portion (brace 12 of Amarasinghe) includes each lateral side of the frame (portions 15 are formed of a malleable wire), and the selected frame portion (12) is bendable (capable of being bent) to cause each lateral side of the frame to push against sides of the cushion. Claim 34 does not require the lateral sides be bent, only that they a capable of being bent (i.e. bendable) and Amarasinghe clearly teaches side projecting members (15) that are capable of being bent to cause each lateral side of the frame to push against sides of the cushion. See: figures 2-4 of Amarasinghe.

In response to Appellant's arguments regarding claims 35 & 36, on page 29, first two paragraphs, that Amarasinghe does not disclose or suggest anything about the stabilizing portion 20 of the brace supporting the cushion 16, the examiner respectfully disagrees. Portion 20 is described by Amarasinghe as the forehead stabilizing portion that is in near contact or contact with the user's forehead thereby limiting movement of the accompanying mask frame and mask cushion towards to the user's face in the

region of the nasal bridge. Thus, portion 20 is a flexible member (i.e. it is a malleable wire) and it is supporting the cushion by limiting the cushions movement.

Appellant's arguments regarding claim 37, on page 29, third paragraph, have not been found convincing because the shell 13 and the brace 12 of Amarasinghe are two separate parts that are coupled together.

Regarding Appellant's arguments to the rejection of claim 38, on page 29, last paragraph, have not been found convincing because the brace 12, which includes the lateral portions 15 is formed of a malleable wire (constructed of 2.5mm gauge mild steel) which is a flexible material (i.e. able to bend without breaking).

Regarding Appellant's arguments to the rejection of claim 40, on page 30, first paragraph, have not been found convincing because the brace 12, which includes the lateral portions 15 is formed of a malleable wire (constructed of 2.5mm gauge mild steel) which is a flexible material (i.e. able to bend without breaking) and they are moveable (capable of being moved) relative to the main body to adjust the sides of the cushion.

Appellants argument to the rejection of claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amarasinghe et al., (WO 02/45784), as applied to claim 19 and 34 above, in view of Gradon et al., (2003/0089373) have been fully considered; however, they have not been found convincing.

Appellants argue that the Examiner has not provided substantial evidence support for finding that Amarasinghe et al. disclose or suggest at least one selected frame portion is engaged with the cushion so that the cushion is adjustable in

accordance with a position of the at least one selected frame portion relative to the main body. This has not been found convincing because, as noted above, the examiner shown the Amarasinghe discloses at least one selected frame portion (12) is engaged with the cushion (16) so that the cushion is adjustable (capable of being adjusted) in accordance with a position of the at least one selected frame portion (12) relative to the main body (13).

Appellants then argue that the examiner has failed to correctly resolve the scope and contents of the prior art, the Examiner has also failed to correctly resolve the differences between the claims and the prior art and has failed to provide a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. However, the examiner respectfully disagrees.

The examiner has pointed out that Amarasinghe discloses all the limitations of claim 21 except the knob to change the relative positioning between the main body and the frame portion.

Gradon teaches a knob (440) that is used to adjust the bridge member (430) and provided a reason for combining the references in that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mask assembly disclosed by Amarasinghe by replacing the stabilizing forehead portion of Amarasinghe with the adjustable forehead stabilizing portion as taught by Gradon because of the reasonable expectation of obtaining a mask assembly that could be adjusted easily and quickly without having to undue the straps.

In response to Appellants' argument that there is nothing in the disclosure of Gradon et al. that suggests that the kabob 440 allows easy and quick adjustment of the bridge member 430 without having to undo the straps, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, it is clear that the adjustment knob of Gradon would provide for quick and easy adjustment of the forehead stabilization portion without having to remove the straps.

Regarding Appellants argument that modifying the brace 12 of Amarasinghe et al. to have a knob 440 such as disclosed by Gradon et al. would make the adjustment more difficult and slower, not easier and quicker has not been found convincing as this bending would require the removal of the straps. The rational underpinning the combination is by replacing the stabilizing forehead portion of Amarasinghe with the adjustable forehead stabilizing portion as taught by Gradon would be desired to obtain a mask assembly that could be adjusted easily and quickly without having to undue the straps.

Regarding Appellant's arguments to the rejection of claims 25, 26 and 28 which were rejected under 35 U.S.C. § 103(a) over Amarasinghe et al. in view of Hellings et al. (U.S. Patent 5,975,079), these arguments have been fully considered but have not been found convincing. Appellant argues that claims 25 & 26 are patentable because

Hellings fails to cure the deficiencies of Amarasinghe and the combination of the references would not result in the claimed inventions.

However, the examiner respectfully disagrees. As noted above, the examiner's position is that there are no deficiencies related to Amarsinghe's teachings. Furthermore, Hellings teaches a mask that is curved and contoured around the mouth and nasal bridge with an inflatable cushion. The reference teaches applying the mask to a user's face and then inflating the cushion, to provide a pneumatic seal. See: col. 3, lines 48-65.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mask disclosed by Amarasinghe by using an inflatable cushion as taught by Hellings, because of the reasonable expectation of obtaining a mask with a pneumatic seal while simultaneously alleviating orbital irritation and eliminating ocular pressure.

Regarding Appellants argument on page 33, second paragraph, that claim 28 requires the at least one element provides for multiple stiffening rates of the cushion upon changes in the force applied to the patient, not upon the rate gas is supplied to the mask, the examiner maintains that the stiffening rate of the cushion taught by Hellings is directly attributable to the rate the gas is supplied to the mask. Thus, by adjusting the gas delivery rate (which would change the force applied to the patient, the cushion stiffening rate would also be adjusted. Thus, the combined references teach a cushion with at least one element providing for multiple stiffening rates as claimed.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Clinton Ostrup/
Examiner, Art Unit 3771

Conferees:

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

/Janet C. Baxter/
TC 3700 TQAS